Pilot Testing and Vernacular Translation of EORTC Patient Satisfaction Questionnaire (PATSAT-C33 and OUT-PATSAT7) at a Tertiary Care Cancer Center in India

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Abstract

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Keywords

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Purpose Pilot testing and translation of the English version of European Organization for Research and Treatment of Cancer (EORTC) patient satisfaction cancer core questionnaire (PATSAT-C33) and complementary outpatient module (OUT-PATSAT7) into two Indian vernacular languages (Hindi and Marathi).

Methods Patients undergoing fractionated radiotherapy for cancer with basic proficiency in respective language were included in the study after written informed consent. The English version of EORTC PATSAT-C33 and OUT-PATSAT7 questionnaire was pilot tested in 20 patients. The questionnaire was then translated into two Indian vernacular languages (Hindi and Marathi) using EORTC translation methodology. This included forward-translation by two independent professional translators into target languages (Hindi and Marathi) to create an intermediate version; back-translation into English by another independent pair of linguistic experts; and harmonization by comparing back-translated versions (English) to the original English version for reconciliation. The EORTC translation group provided suggestions and proofread the reconciliated versions (Hindi and Marathi) which were then administered to 20 patients in each language. Semistructured interviews were conducted for patients to identify problems in understanding the translation versions to make appropriate corrections/modifications to the questionnaire.

Results Pilot testing of English version of PATSAT-C33 and OUT-PATSAT7 did not pose any major difficulty leading to subsequent translation into both target languages (Hindi and Marathi). Reconciliated version of the translated questionnaires was arrived at after incorporating suggestions and proofreading by the EORTC translation group.

Pilot testing of the reconciled questionnaires (Hindi and Marathi) did not identify major problems in understanding, difficult/confusing words, or upsetting questions leading to the adoption of the reconciled version as final translated questionnaire without further modifications.

Conclusion   The English version of PATSAT-C33 and OUT-PATSAT7 has been successfully translated into Hindi and Marathi languages using standardized EORTC methodology. Psychometric properties of the same are currently being tested for validation in a larger Indian cohort.

Introduction

Patient satisfaction has been increasingly recognized as an effective yardstick for assessing quality of health care systems.[1] Patient-reported experience measures (PREMs) have garnered significant attention in recent years due to growing emphasis on patient-centric approaches.[1,2] Various PREMs have been designed to assess satisfaction in patients under oncologic care. The OUTPATSAT-35 is one such validated questionnaire (adapted from INPATSAT-32 for inpatients) for patients undergoing ambulatory oncologic treatment[3] such as radiotherapy (RT) or chemotherapy (CT), which was recently translated[4] and validated[5] in two Indian vernacular languages (Hindi and Marathi) in a low-middle income country (LMIC) setting. Given remarkably similar domains and significantly overlapping items between INPATSAT-32 and OUTPATSAT-35 (RT and CT), the European Organization for Research and Treatment of Cancer (EORTC) has now developed a 33-item satisfaction with cancer care core questionnaire (PATSAT-C33) and a 7-item complementary module (OUT-PATSAT7) specific for outpatient care setting[6] and have subsequently been applied in patients from 11 countries (in 10 languages).[7] The EORTC PATSAT-C33 and OUT-PATSAT7 questionnaires are currently undergoing phase IV cross-cultural validation and psychometric assessment in various geo-ethnic populations across the globe.

Aim

This study was aimed at pilot testing and translation of the English version of EORTC PATSAT-C33 and OUT-PATSAT7 into two Indian vernacular languages (Hindi and Marathi).

Material and Methods

Eligibility

Adult patients (18 years and above) undergoing fractionated RT ($\geq$ 10 fractions) on ambulatory basis in the definitive, adjuvant, or palliative setting for a pathologically proven diagnosis of cancer with a working knowledge of English, Hindi, or Marathi were included in the study after written informed consent. Patients who were unable to read or understand the questionnaire (illiterate or cognitively impaired) were excluded. The study was conducted at a large tertiary care cancer center in Western India and was duly approved by the Institutional Ethics Committee that functions in accordance with the Declaration of Helsinki. The study received competitive intramural research funding provided by the institute which had no role in the study design, conduct, analysis, or reporting of results. The study is registered with the Clinical Trials Registry of India (CTRI/2020/12/029685).

Questionnaires

The EORTC PATSAT-C33 (►Supplementary File S1, available in online version) is a core questionnaire comprising of 33 close-ended questions, divided into four sections to evaluate the concerned health workers—doctors; RT technicians (for outpatient care) or nurses (for inpatient care); services and care organization; and overall. A five-point Likert scale with the following categories—(1) "poor"; (2) "fair"; (3) "good"; (4) "very good"; and (5) "excellent" is used for documenting response to individual items in the questionnaire, with a higher score indicating greater satisfaction with care and vice versa. The specialized outpatient module, OUT-PATSAT7 (online ►Supplementary File S1), deals with specific facets of ambulatory cancer care (daycare surgery, CT, and outpatient RT). In addition to the above, patients were also simultaneously administered the EORTC multidimensional quality-of-life (QOL) core questionnaire (QLQ-C30) in the same language as PATSAT-C33 and OUT-PATSAT7.

Methodology

The study methodology is briefly described and summarized in ►Fig. 1. The index English version of the questionnaires (PATSAT-C33 and OUT-PATSAT7) was administered to 20 patients with basic proficiency in English within 3 days ($\pm$) of completion of their planned RT regimen. After filling the questionnaires, an interview was conducted using a semistructured format to assess appropriateness of the items in the questionnaire in the tested population, which was documented *patient-wise* and then reorganized under the same structured format but for each item (*item-wise*). After pilot testing, translation of the questionnaire was done according to standardized and validated EORTC methodology for such translations (►Fig. 1).[8] Reconciliation was done by a third linguistic expert after merging information from both forward-translated versions. The intermediate version of either language was then back-translated and compared with the original questionnaire for harmonization. The
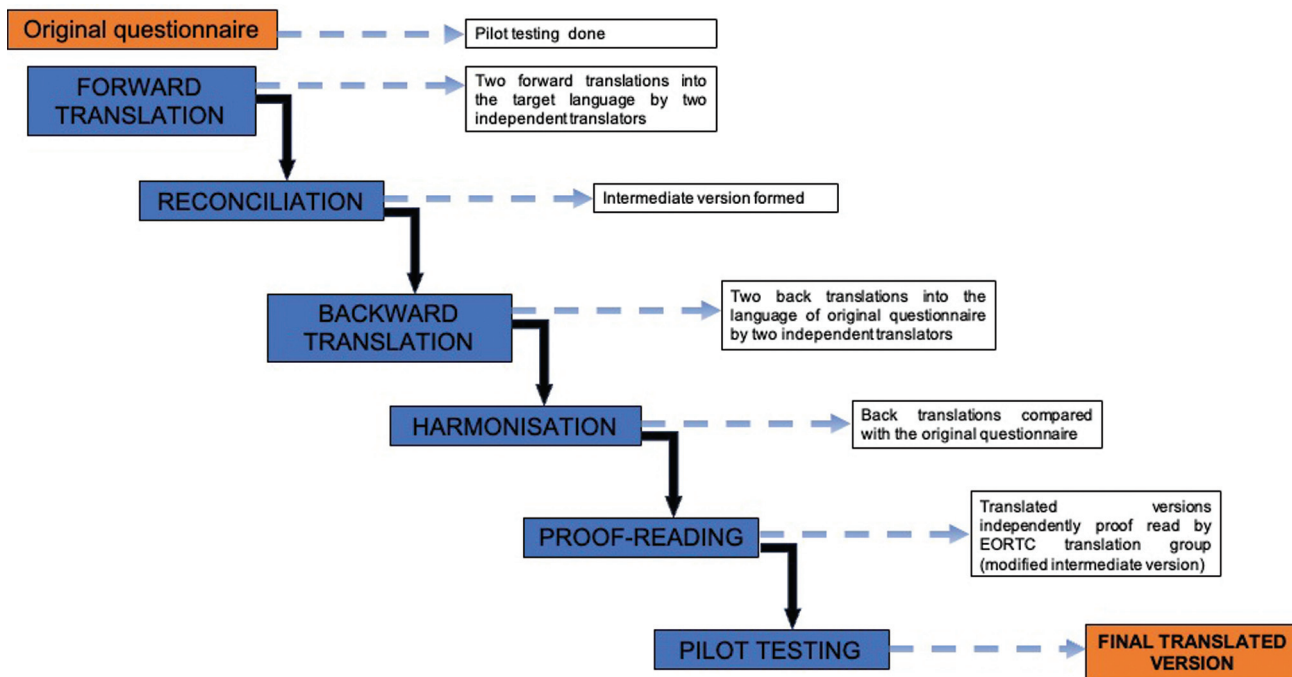
Fig. 1 Flowchart describing standard European Organization for Research and Treatment of Cancer (EORTC) translation methodology.

intermediate versions were independently proofread by the EORTC translation group who provided suggestions for further minor modifications (modified intermediate version). This was subsequently administered to 20 patients each (basic proficiency in respective vernacular language) for pilot testing. As per standard methodology, all patients underwent semistructured interviews as mentioned above. Patient concerns were addressed and suggestions if any were incorporated to create the final translated version of the questionnaire in the respective vernacular language.

Statistical Analysis

Data completeness was calculated for EORTC PATSAT-C33 and OUT-PATSAT7 as well as QLQ-C30 questionnaire items. QLQ-C30 item scores were converted to raw scores in accordance with the EORTC recommendations.[9] All statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 24.0.

Results

A total of 60 patients who filled these questionnaires (20 in each language—English, Hindi, and Marathi) constitute the present study cohort. Sociodemographic factors, clinical parameters, and treatment characteristics of included patients are briefly summarized in ►Table 1. None of the 20 patients included in pilot testing of the English version of PATSAT-C33 and OUT-PATSAT7 questionnaires reported any problems in understanding, difficult/confusing words, or upsetting questions during semistructured interviews. Translation of the questionnaires was done into the two Indian vernacular languages, Hindi and Marathi (►Fig. 1), that are commonly spoken in Western India. The intermediate versions in both vernacular languages were

proofread by the EORTC translation group and their suggestions incorporated in the modified intermediate versions which was used for pilot testing in 20 patients each with basic proficiency in Hindi and Marathi languages in conjunction with language-appropriate version of EORTC QLQ-C30. Some translated words (in Hindi and/or Marathi) in the PATSAT-C33 and OUT-PATSAT7 questionnaires were deemed difficult to understand by patients during semistructured interviews. These were related to vernacular translation of few specific words (privacy, attention, consultation, provision, and physiotherapist) which could not have been simplified further without losing their essence and meaning. None of the patients suggested further changes (corrections/modifications) to the content or wording, hence, the modified intermediate versions were adopted as the final translated questionnaires (online ►**Supplementary Files S2 and S3**, respectively) in both Hindi and Marathi languages, respectively.

All patients ($N = 60$) responded to all the items of EORTC PATSAT-C33 and OUT-PATSAT7 as well as QLQ-C30 questionnaires resulting in full compliance with zero data attrition. Summary satisfaction scores in terms of mean scores with standard deviation (SD) and median scores (range) for various scales of all tested domains in PATSAT-C33 and OUT-PATSAT7 are reported in ►**Table 2**. Satisfaction scores were generally high for all scales with highest mean scores (4.1) obtained for Q32 (environment) and Q33 (general satisfaction) while lowest mean score (2.9) seen for waiting time for medical appointment (Q36). The mean ($\pm$ SD) and median (range) scores of all individual questions of QLQ-C30 for the entire study cohort ($N = 60$) are summarized in ►**Table 3**. Higher scores for functional and global health status scales reflect healthy level of living, while lower scores for symptom scale reflects better symptom control. There were no

Table 1 Characteristics of the study cohort (N = 60)

Characteristics	Number (%) of patients
Age	
18–40 y	26 (43.3)
41–60 y	26 (43.3)
> 60 y	08 (13.4)
Gender	
Female	16 (26.7)
Male	44 (73.3)
Cancer site	
Brain tumor	35 (58.3)
Head-neck cancer	19 (31.7)
Lung cancer	03 (05.0)
Esophageal cancer	01 (01.7)
Penile cancer	01 (01.7)
Cervical cancer	01 (01.7)
Stage of disease	
Early disease/favorable prognosis	21 (35)
Advanced disease/ unfavorable prognosis	39 (65)
Karnofsky Performance Status (KPS)	
KPS = 70	05 (08.4)
KPS = 80	32 (53.3)
KPS = 90	23 (38.3)
Educational qualification	
Primary/middle school	10 (16.7)
Secondary/higher secondary school	28 (46.7)
Graduation	18 (30.0)
Postgraduation	04 (06.6)
Occupation	
Student/unoccupied/retired	21 (35.0)
Farming	01 (01.7)
Business	04 (06.6)
Salaried work	34 (56.7)
Working status (n = 39)	
Working during RT	09 (20.5)
Break from work during RT	30 (79.55)
Economic status (World Bank fiscal year 2018)	
Low-income group	19 (31.7)
Lower middle-income group	22 (36.7)
Upper middle-income group	11 (18.3)
High-income group	03 (05.0)
Not available/not known	05 (08.3)

Abbreviation: RT, radiotherapy.

significant correlations between QLQ-C30 domains and PATSAT-C33/OUT-PATSAT7 scales indicating that they assess different aspects of patient-reported measures. While QLQ-C30 measures specific aspects of cancer symptoms and treatment outcomes from the patient's perspective (patient-reported outcome measures), PATSAT questionnaires measure patient's view of health service experiences (PREM) allowing direct feedback to health care administrators (planners and policy makers) to improve health care system.

Discussion

Patient satisfaction, a key indicator of health care quality, requires comprehensive yet dedicated tools to assess patient experience through various phases of care across diverse health care settings. Although several PREMs have been designed, developed, and described in the indexed medical literature, only a few pertain to oncologic care and even fewer have been translated and validated in Indian vernacular languages.[4,5,10–14] One such questionnaire (OUTPATSAT-35RT) that assesses patient satisfaction on ambulatory RT was recently translated and validated in two Indian vernacular languages.[4,5] However, given that cancer care spans across different settings including inpatient care and outpatient services, it was deemed necessary to revise the existing questionnaires to comprehensively assess patients' perceived quality of care across cancer care settings to create an overarching cancer care questionnaire. Brédart et al reported the initial steps taken to produce a satisfaction with cancer care core questionnaire (applicable for inpatient and outpatient settings) and a complementary cancer outpatient satisfaction with care module, which later resulted in the EORTC PATSAT-C33 and OUT-PATSAT7 questionnaires, respectively.[6] The latter module was intended to cover outpatient satisfaction with daycare surgery, ambulatory RT, outpatient CT, and home-based cancer therapy. A preliminary list of cancer issues to complement IN-PATSAT32 and specifically address outpatient setting was prepared after reviewing multiple questionnaires in literature.[3,15,16] After several rounds of revision to eliminate redundancy, ensure clarity, and define cancer care issues with approximately the same level of abstraction and specificity, a consolidated list of 88 issues was presented to patients and health care providers for rating the appropriateness of items using semistructured interviews. Items were deleted depending on reported low relevance and low priority. The remaining 57 items were then operationalized as questionnaire items into preliminary questionnaires (cancer core and outpatient modules). In the next developmental phase, the preliminary satisfaction questionnaires were translated into 10 languages and pretested in 11 countries in order to identify/solve potential problems in its administration and to identify redundant or missing issues.[7] This led to the retention of 40 items which was operationalized into EORTC PATSAT-C33 and OUT-PATSAT7 questionnaires after testing of scale properties. A large-scale phase IV cross-cultural validation study is now

Table 2 Mean with standard deviation (SD) and median (range) scores of individual questions in EORTC PATSAT-C33 and OUTPATSAT7 in all three languages combined ($N = 60$)

No:	Question	Mean (SD)	Median (range)
PATSAT-C33			
	Doctors		
1	Their awareness of the care and treatment you received previously?	3.95 (1.0)	4 (2–5)
2	The attention they gave to your physical symptoms?	3.9 (0.9)	4 (2–5)
3	Their thoroughness in treating your physical symptoms?	3.9 (0.9)	4 (1–5)
4	The information they gave you about your illness?	3.9 (1.0)	4 (1–5)
5	The information they gave you about your medical tests and treatment?	4.0 (1.0)	4 (1–5)
6	The attention they gave to your opinion about the choice of your treatment (in case of possible choices)?	3.6 (1.0)	4 (1–5)
7	The interest they showed in you as a person?	3.9 (1.0)	4 (1–5)
8	The comfort and support they gave you?	4.0 (1.1)	4 (1–5)
9	The frequency of their visits/consultations?	3.8 (1.0)	4 (2–5)
10	The time they devoted to you?	3.9 (1.0)	4 (2–5)
	Nurses or radiotherapy technicians		
11	The attention they gave to your physical comfort?	3.8 (0.9)	4 (2–5)
12	The information they gave you about your care and treatment?	3.9 (1.1)	4 (1–5)
13	The advice they gave you on managing your physical symptoms?	3.8 (1.0)	4 (1–5)
14	The interest they showed in you as a person?	3.8 (1.0)	4 (1–5)
15	The comfort and support they gave you?	3.8 (1.0)	4 (1–5)
16	Their promptness in answering your specific requests?	3.7 (1.0)	4 (1–5)
17	The time they devoted to you?	3.8 (1.0)	4 (1–5)
	Services and care organization		
18	The ease of recognizing the roles and responsibilities of the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.) involved in your care?	3.8 (0.9)	4 (2–5)
19	The exchange of information between the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.)?	3.7 (0.9)	4 (2–5)
20	The way doctors, nurses, and other caregivers involved in your care seem to work together as a team?	3.9 (0.9)	4 (2–5)
21	The exchange of information with other care services in the community (general practitioner, home care, nursing house, social services, etc.)?	3.4 (0.9)	4 (1–5)
22	The kindness and helpfulness of the technical, reception, laboratory personnel, etc.?	3.8 (1.0)	4 (2–5)
23	The information provided on the scheduling of medical tests, treatment, or care?	3.8 (0.9)	4 (2–5)
24	The information provided on the overall supportive services available (social, psychological, physiotherapy, dietitian services, support group, etc.)?	3.6 (1.1)	4 (1–5)
25	The information provided by doctors, nurses, and other caregivers on things you could do to improve your health or prevent illness?	3.9 (0.9)	4 (2–5)
26	The waiting time for obtaining results of medical tests?	3.1 (1.0)	3 (1–5)
27	The waiting time for undergoing medical tests and/or treatments?	3.1 (1.0)	3 (1–5)
28	The privacy given when you were examined or treated?	3.7 (1.0)	4 (1–5)
29	The opportunity for your family or those close to you to be involved in your care (talking to doctors, receiving disease and care information, etc.)?	3.7 (1.0)	4 (1–5)
30	The ease of access (parking, means of transport, etc.)?	3.2 (1.2)	3 (1–5)
31	The ease of finding your way to the different departments in the hospital?	3.5 (1.1)	4 (1–5)
32	The environment of the building (cleanness, spaciousness, calmness, etc.)?	4.1 (1.0)	4 (2–5)

(*Continued*)

Table 2 (*Continued*)

No:	Question	Mean (SD)	Median (range)
	General		
33	How would you rate the care you received in this hospital?	4.1 (1.0)	4 (2–5)
OUT-PATSAT7			
34	The opportunity to see the same caregivers when you come to the outpatient clinic?	3.5 (1.0)	3.5 (2–5)
35	The ease of arranging medical appointments at convenient times?	3.5 (1.0)	4 (2–5)
36	The waiting time before obtaining a medical appointment?	2.9 (1.2)	3 (1–5)
37	The ease of communicating with the hospital services from home?	3.2 (1.2)	3 (1–5)
38	The information provided about what you should/should not do after you leave your hospital appointment?	3.7 (1.0)	4 (2–5)
39	The information on who to contact if you are worried after you leave your hospital appointment?	3.5 (1.1)	4 (1–5)
40	The provision of follow-up by the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.) after treatment?	3.8 (1.0)	4 (2–5)

Abbreviation: EORTC, European Organization for Research and Treatment of Cancer.

Table 3 Mean with standard deviation (SD) and median (range) scores of different domains of EORTC QLQ-C30 questionnaire in all three languages combined (*N*= 60)

Domain[a]	Mean (SD)	Median (range)
Functional domain		
Physical functioning scale	76.3 (20.0)	80.0 (0–100)
Role functioning scale	78.0 (23.1)	83.3 (0–100)
Emotional functioning scale	68.9 (23.0)	66.7 (8.3–100)
Cognitive functioning scale	74.7 (25.0)	83.3 (16.7–100)
Social functioning scale	71.7 (28.0)	83.3 (0–100)
Symptom domain		
Fatigue scale	34.8 (24.4)	33.3 (0–100)
Nausea and vomiting scale	30.0 (28.1)	16.7 (0–100)
Pain scale	32.5 (26.2)	33.3 (0–100)
Dyspnea scale	16.1 (23.3)	0 (0–100)
Sleep scale	30.5 (35.9)	33.3 (0–100)
Appetite loss scale	39.4 (31.5)	33.3 (0–1000
Constipation scale	30.5 (29.6)	33.3 (0–100)
Diarrhea scale	17.2 (28.4)	0 (0–100)
Financial domain		
Financial difficulties scale	31.7 (30.3)	33.3 (0–100)
Global health domain		
Global health status scale	62.5 (22.5)	58.3 (8.3–100)

Abbreviation: EORTC, European Organization for Research and Treatment of Cancer.
[a]Higher scores of functional, financial, and global health statuses reflect better quality of life, while lower scores of symptom scales reflect better symptom control.

underway globally to establish psychometric properties of the questionnaire during which these questionnaires are being administered to four main groups of patients based on the cancer care settings at three assessment times. Cross-cultural applicability and acceptability, reliability, validity, responsiveness to change, and cross-cultural invariance of psychometric properties of these questionnaires will be assessed and reported in due course.

Compared to other satisfaction tools, PATSAT-C33 and OUT-PATSAT7 questionnaires are considered to be much

more inclusive and comprehensive in context with care settings.[6] The present study pilot tested and translated the English version of EORTC PATSAT-C33 and OUT-PATSAT7 into two Indian vernacular languages (Hindi and Marathi), which are commonly spoken in Western India. There was a general trend of high satisfaction scores which can be somewhat misleading due to relatively small sample size and potential bias based on patient's perception of likely negative impact on further treatment in case of reporting low levels of satisfaction. Lowest satisfaction scores pertained to questions concerning waiting times—for appointments (mean score 2.9) and for daily treatments (mean score 3.1). This is understandable as the study was conducted in a busy RT department with high footfalls that poses major challenges in providing early appointments and efficient scheduling of visits during RT on a daily basis.

Limitations

Although the outpatient module (OUT-PATSAT7) is applicable to different outpatient settings, this study was restricted to patients undergoing ambulatory RT only limiting generalizability. The present cohort comprised mainly of patients with brain tumors and head-neck cancers with minimal representation of other commonly prevalent cancers (breast and cervix) in India. Only patients receiving fractionated RT (≥ 10 fractions) were eligible, excluding patients receiving hypofractionated regimens (typically 1–5 fractions) including stereotactic radiosurgery or stereotactic body RT limiting applicability in that subset. Finally, the questionnaire does not address some of the unique challenges faced by health care systems in resource-constrained LMIC settings.

Conclusion

This study successfully completed pilot testing and translation of EORTC PATSAT-C33 and OUT-PATSAT7 questionnaires into two Indian vernacular languages (Hindi and Marathi) using standardized methodology. Psychometric properties of the questionnaire are presently being assessed for validation testing in a larger Indian cohort.

Ethical Approval

The study was approved by the Institutional Ethics Committee of Tata Memorial Centre, Mumbai, Maharashtra, India that functions in accordance with the Declaration of Helsinki.

Funding

Conflict of Interest

None declared.

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